

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/459,385 | 12/02/99 | EDWARDS | S 10390-0002-2 |

QM12/0720
OBLON SPIVAK MCCLELLAND MAIER &
NEUSTADT PC
1755 JEFFERSON DAVIS HIGHWAY FOURTH FL
ARLINGTON VA 22202

| | |
|-----------------------|--------------|
| EXAMINER | |
| PEFFLEY, M | |
| ART UNIT | PAPER NUMBER |
| 3739 | |
| DATE MAILED: 07/20/01 | |

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/459,385

Applicant(s)

EDWARDS ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Applicant's preliminary amendment, filed December 2, 1999, has been considered. In particular, this application claims to be a continuation of US Application No. 09/364,203, which is a continuation of US Application No. 08/623,652. However, the '652 application had Figures 13-15, whereas the instant application only has figures through Figure 12. This difference in disclosures prevents the instant application from being a continuation of the '652 application. The '203 application was not available for review by the examiner at the time of this Office action. Applicant is respectfully requested to review the file contents of the parent applications and set forth the continuing data accordingly.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 33 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 33 positively recites tissue which is non-statutory subject matter. Applicant is required to avoid positive recitation of the tissue using language such as "adapted to be inserted into tissue, adapted to penetrate tissue and adapted to extend to a selected mass".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is unclear as to the scope of the invention in that it recites tissue. It is not clear if the tissue is to be positively recited as part of the invention, and tissue is non-statutory subject matter. This rejection will be obviated if amended as suggested in the 35 USC 101 rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Rydell ('908).

The Rydell probe system includes an elongate member (12), an electrode deployment device located within the elongate member, a retractable electrode (42) which is inserted into tissue with a radius of curvature, and a handle member for supporting the elongate member and deployment device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3739

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Abele et al ('311) or Durgin, Jr et al ('222) in view of the teaching of Rydell ('908).

Abele et al discloses a probe system including an elongate member (20), a handle (17,18) at the proximal end, an electrode deployment means located in the elongate member to advance the electrode into tissue. The only feature not expressly taught by Abele et al is the curvature of the needle.

Similarly, Durgin, Jr et al disclose a device comprising an elongate member (10) with a handle and an advancement means located in the elongate member. There is also a retractable electrode (67) which is advanced into tissue and may be retracted into the elongate member. The only feature not expressly taught by Durgin, Jr et al is a needle having curvature.

As addressed in the 35 USC 102 rejection, Rydell provides a probe which is very similar to the Abele et al and Durgin, Jr et al devices. In particular, Rydell teaches that it is known to provide the retractable needle electrode with curvature so that it may be deployed into tissue.

To have provided either the Abele et al or the Durgin, Jr devices with a curved electrode for penetration of tissue would have been an obvious design consideration for one of ordinary skill in the art in view of the teaching of Rydell.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7 and 17 of U.S. Patent No. 5,935,123. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent claims and the application claim recite essentially the same structure with only minor differences.

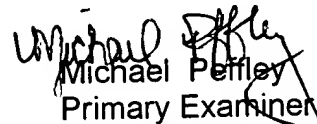
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Application/Control Number: 09/459,385
Art Unit: 3739

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
July 18, 2001